

PATIENT GROUP DIRECTION (PGD)

Administration of Midazolam Oromucosal Solution by Registered Nurses on Ward 3 King's Lodge at FNCH

Documentation details

Reference no:	UHDB152
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Change history

Version number	Change details	Date
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Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Dr Uditha Jayatunga	Rehabilitation Consultant
Maradel Rahman	Senior Sister
James Kerr	Divisional Pharmacist

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Ward 3 Kings Lodge, Florence Nightingale Community Hospital
Limitations to authorisation

Organisational Authorisation (legal requirement).			
Role	Name	Sign	Date
Pharmacist: Medicines Safety Officer <i>Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)</i>	James Hooley	Signed copy held by Pharmacy	16/03/2022

Additional signatories (required as per legislation and locally agreed policy)			
Role	Name	Sign	Date
Divisional Lead Pharmacist <i>Clinical Pharmacist from PGD working group</i>	James Kerr	Signed copy held by Pharmacy	04/03/2022
Rehabilitation Consultant <i>Doctor</i>	Dr Uditha Jayatunga	Signed copy held by Pharmacy	16/02/2022
Senior Sister <i>Registered Professional representing users of the PGD</i>	Maradel Rahman	Signed copy held by Pharmacy	16/02/2022
CD Accountable Officer	Clive Newman	Signed copy held by Pharmacy	09/03/2022

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered Nurse with a current NMC registration
Initial training	<ul style="list-style-type: none"> - Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment
Competency assessment	<p>Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions</p> <p>Have read and understood <i>Recommendations for Treatment of Tonic-Clonic seizure and Status Epilepticus on King's Lodge.</i></p> <p>Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.</p>
Ongoing training and competency	<p>Annual Medicines Safety Training (essential to role)</p> <p>Review/repeat initial training above when this PGD is revised</p>
<p><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</i></p>	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Acute epileptic seizures lasting more than 5 minutes (see <i>Recommendations for Treatment of Tonic-Clonic seizure and Status Epilepticus on King's Lodge</i>).
Criteria for inclusion	For an adult with acute epileptic seizures lasting more than 5 minutes (see <i>Recommendations for Treatment of Tonic-Clonic seizure and Status Epilepticus on King's Lodge</i>). Patients 16 years and above
Criteria for exclusion	Previous sensitivity or intolerance to the drug or any ingredient Patient under 16 years old Acute lung disorders or breathing difficulties, severe respiratory depression Marked neuromuscular respiratory weakness Myasthenia Gravis Sleep apnoea syndrome Severe hepatic impairment
Cautions including any relevant action to be taken	Only give in acute epileptic seizures lasting more than 5 minutes Cardiac disease, hypothermia, hypovolemia Complex partial status epilepticus or repeated partial seizures with normal consciousness and complete recovery between seizures - follow clinical guideline and seek senior medical advice before treatment.
Action to be taken if the patient is excluded	<i>See Recommendations for Treatment of Tonic-Clonic* seizure and Status Epilepticus on King's Lodge</i> Record reasons for exclusion in patient notes Advise patient on alternative treatment Refer for medical staff for review if available. Dial 999 if seizure lasts more than 5 minutes
Action to be taken if the patient or carer declines treatment	Document advice given Advise patient on alternative treatment. Refer to medical staff as soon as possible. Dial 999 if seizure lasts more than 5 minutes
Arrangements for referral for medical advice	Discuss with on call medical cover service. If seizure continues, inform Emergency Department and transfer patient.

5. Description of treatment

Name, strength & formulation of drug	Midazolam 10mg in 2ml oromucosal solution
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Legal category	Prescription only medicine (POM) & CD3
Route / method of administration	Buccal administration
Indicate any off-label use (if relevant)	Off-label. This formulation is not licensed for use in patients aged 18 years and over but is supported by BNF dosing.
Dose and frequency of administration	10 mg buccal administration and repeat once 10 minutes after first dose was administered if seizure continues
Duration of treatment	If seizure continues 10 minutes after first dose was administered, ring 999 and transfer the patient (see <i>Recommendations for Treatment of Tonic-Clonic* seizure and Status Epilepticus on King's Lodge</i>)
Quantity to be supplied (leave blank if PGD is administration ONLY)	n/a
Storage	Stock must be securely stored according to UHDB CD policy: Store in CD cupboard and document in CD register.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Adverse reactions	<p>The following side effects are common:</p> <ul style="list-style-type: none"> • Decreased alertness • Depression • Fatigue, dizziness • hypotension • muscle weakness • respiratory depression • vomiting <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	Not appropriate in advance of treatment. The package insert can be provided (or printed from www.medicines.org.uk) may be supplied if the patient has questions following recovery.
Patient advice / follow up treatment	Refer to epilepsy nurse for further advice as soon as available.

Records	<p>Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following:</p> <ul style="list-style-type: none"> • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether <u>supplied and/or administered</u> and that this was done via Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous.</p> <p>If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.</p>
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6. Key references

Key references	<ul style="list-style-type: none"> • Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 • <i>Recommendations for Treatment of Tonic-Clonic* seizure and Status Epilepticus on King’s Lodge</i>
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7. Registered health professional authorisation sheet

**PGD Name [version]: King’s Lodge - Midazolam – Status Epilepticus [V1.0]
PGD ref: UHDB152**

Valid from: 16/03/2022 Expiry date: 15/03/2025

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read **MUST** match this authorisation form.

Registered health professional

By signing this patient group direction you are indicating that

- a) You agree to and understand all content and commit to only work within this framework.
- b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
- c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.